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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,315

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EXAMINER

HAGEDORN, MICHAEL E

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,315	Applicant(s) STRADELLA ET AL.	
	Examiner Michael Hagedorn	Art Unit 3754	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 10/564,315.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12 January 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 1 is objected to because of the following informalities: the word "characterised" appears to be the misspelling of the word characterized. Appropriate correction is required.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1 – 19 are rejected on the ground of nonstatutory double patenting over claims 1 - 15 of U. S. Patent No. 7,275,660 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

4. Claims 1 - 19 provisionally rejected on the ground of nonstatutory double patenting over claims 1 - 40 of copending Application No. 10/564,748. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

5. Claims 1 – 19 are provisionally rejected on the ground of nonstatutory double patenting over claims 1 - 19 of copending Application No. 10/542,507. This is a

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provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1 – 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. The term "part" in claim 1, 8, 17 and 19 is a relative term which renders the claim indefinite. The term "one part" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 1, 8, 15, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Ouyang et al. (US Patent Publication 2004/0149773).

11. In re claim 1, Ouyang et al. with reference to figures 1 & 2 below discloses a dose indicator for a fluid product dispensing device (1), including at least one rotary counting means (142) capable of being rotated, said at least one counting means including indicating means (141), showing the number of doses dispensed or remaining to be dispensed, said at least one counting means being actuated by an actuating member (143) which itself is actuated by a transmission element (144) suitable to cooperate with a part (149) of said dispensing device (1) at each actuation of the latter, characterized in that said dose indicator includes adaptation means (160 & 159) located between said transmission element (144) and said part (149) of said dispensing device (1), said adaptation means (160 & 159) being movable and/or deformable in order to accurately predetermine, during assembly of the dispensing device (1), the distance at rest between said transmission element (144) and said part (149) of dispensing device (1).

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12. In re claim 8, Ouyang et al. discloses wherein said transmission element (144) is a shoulder attached to a flexible tab (154), and cooperating with a part (149) of the fluid product dispensing device (1) which is movable during its actuation.

13. In re claim 15, Ouyang et al. discloses wherein said indication means (147) are number and/or symbols.

14. In re claim 18, Ouyang et al. discloses fluid product dispensing device (1) that includes a product reservoir (21) and a dispensing member (22) such as a pump or valve mounted on said reservoir (21), characterized in that it includes a dose indicator.

15. In re claim 19, Ouyang et al. discloses wherein the dose indicator is actuated by a part (149) of the dispensing device (1) which is moved during actuation of device (1) and which cooperates with a transmission element (144) of said indicator (142).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 1 – 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horlin (WO 01/37909 A1) in view of Fairbairn (GB 1,336,014).

19. Horlin discloses an inhaler cartridge (4) that dispenses by pressing downwardly inside a holder channel (3) in order to trigger the dispensation (see figure 7) through passage (6), with a counter mechanism (2) with a cap (7) with a viewing window (10) to view a spiral set of number (21) to assist the user in knowing how many doses are used or left, the pin (32) is actuated when the inhaler cartridge (4) is pressed downwardly into the holder channel (3), the pin (32) flexes a tab (33) that flexes before the actuation of the inhaler cartridge (4), which in turn changes the viewed number (see figure 3a) with the use of the second relatively stiff flexible tabs (25 - 26) that actuate after the rotary wheel has commenced rotating, the control wheel prevented from over actuating by a key slot (34 - 35), which will only allow the control wheel to actuate a certain distance, the control wheel prevented from rotating in the wrong direction by the end tabs (30 – 31), the entire counting device (2) integrated and assembled as one piece (7 – 9) (see figure 5).

However, Horlin fails to disclose the counting wheel displaceable in rotation, a slide member that is displaceable in translation, to allow the counting wheel to display rows and columns of numbers by translating the slide member at least every so often, the slide member having a projection that cooperates with a channel in the counting

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wheel to track, drive and translate the slide member appropriately, the channel being preferably spiral shaped, slide member and counting one integrated piece.

Although, Fairbairn with reference to figures 1 - 3 teaches a slide member (8) that is integrated with a counting wheel (4), the slide member having a viewing window (12) that shows the various rows and columns of numbers on the counting wheel at the appropriate intervals of actuation, the slide member's viewing window moving by the engagements and movement of the spiral channel (7) on the counting wheel that interacts with the tooth (9) from the slide member (8). Therefore, it would have been obvious to one ordinary skill in the art at the time of the invention to implement Fairbairn's teaching into Horlin's because Fairbairn teaches a way to utilize the entire counting wheel and not just its outer rim for counting dosages, which can ultimately lead to a smaller counter, which is advantageous in a variety of applications.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hagedorn whose telephone number is (571)270-5705. The examiner can normally be reached on 7am - 5pm; Mon thru Fri except federal holidays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (571)270-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./
Examiner, Art Unit 3754

/Kevin P. Shaver/
Supervisory Patent Examiner, Art Unit 3754